

Attorney Docket No.: 6116.200-US
Application No.: 09/757,788
Filed: January 10, 2001
Inventors: Keith Anderson et al.
Express Mail Label No.: EV 732211985 US

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of the claims in the application:

Listing of Claims

Claim 1 (Previously presented) A liquid formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic substituent to said GLP-1 compound is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 μm .

Claim 2 (Previously presented) The formulation of claim 1 wherein said GLP-1 compound to which a lipophilic substituent is attached is exendin or an analog thereof or a GLP-1 analogue.

Claim 3 (Previously presented) The formulation of claim 2 wherein said GLP-1 compound to which a lipophilic substituent is attached is exendin-3, exendin-4 or $\text{Arg}^{34}\text{-GLP-1(7-37)-OH}$.

Claim 4 (Cancelled)

Claim 5 (Previously presented) The formulation of claim 1 wherein said lipophilic substituent is hexadecanoyl.

Claim 6 (Previously presented) The formulation of claim 1 wherein a spacer is present.

Claim 7 (Previously presented) The formulation of claim 6 wherein said spacer is $\gamma\text{-Glu}$ or $\beta\text{-Ala}$.

Claim 8 (Previously presented) The formulation of claim 1 wherein said GLP-1 compound with a lipophilic substituent attached via a spacer is $\text{Arg}^{34}\text{Lys}^{26}(\text{N}^{\epsilon}\text{-(}\gamma\text{-glutamyl(N}^{\alpha}\text{-hexadecanoyl)))-GLP-1(7-}$

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37)-OH, Arg¹⁸, Leu²⁰, Gln³⁴, Lys³³ (N^ε-(γ-aminobutyroyl(N^α-hexadecanoyl))) Exendin-4-(7-45)-NH₂ or Arg³³, Leu²⁰, Gln³⁴, Lys¹⁸ (N^ε-(γ-aminobutyroyl(N^α-hexadecanoyl))) Exendin-4-(7-45)-NH₂.

Claims 9-14 (Cancelled)

Claim 15 (Previously presented) The formulation of claim 1, wherein said formulation is a solution or a suspension.

Claim 16 (Previously presented) The formulation of claim 1, wherein said formulation includes between 0.1 to 100 mg/ml of said GLP-1 compound.

Claim 17 (Cancelled)

Claim 18 (Previously presented) The formulation of claim 1, wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of between 1-5 μm.

Claim 19 (Previously presented) The formulation of claim 1, wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of between 1-3 μm.

Claim 20 (Cancelled)

Claim 21 (Previously presented) The formulation of claim 27, wherein said formulation contains between 50-100 % w/w of said GLP-1 compound.

Claim 22 (Previously presented) The formulation of claim 27, wherein said formulation contains between 75-100 % w/w of said GLP-1 compound.

Claim 23 (Previously presented) The formulation of claim 27, wherein said formulation contains between 90-100 % w/w of said GLP-1 compound.

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Claim 24 (Cancelled))

Claim 25 (Previously presented) The formulation of claim 27, wherein said formulation contains a mass median aerodynamic diameter of aerosol particles of between 1-5 μm .

Claim 26 (Previously presented) The formulation of claim 27, wherein said formulation contains a mass median aerodynamic diameter of aerosol particles of between 1-3 μm .

Claim 27 (Previously presented) A dry formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic substituent to said GLP-1 compound is optionally via a spacer and wherein said formulation contains a mass median aerodynamic diameter of aerosol particles of less than 10 μm .